

REMARKS

This responds to the Office Action dated December 20, 2006 (hereinafter “Office Action”), and the references cited therein.

Claims 1, 3, 8, 15, and 19 are currently amended. No claims are currently canceled or added. Accordingly, claims 1-6 and 8-26 remain pending in this patent application. Applicant submits that the amendments to the claims are fully supported by the patent application as originally filed, and no new matter has been added.

Applicant hereby respectfully requests further examination and reconsideration of the application in view of the foregoing amendments and following remarks.

§112 Rejection of the Claims

1. Claims 1-6 and 24 were rejected under 35 U.S.C. § 112, second paragraph, for indefiniteness. Applicant has amended such claims to further define the “drive grooves,” as requested by the Office Action. Reconsideration and withdrawal of this basis of rejection is respectfully requested.

§102 Rejection of the Claims

2. Claims 1-6, 8-12, 14-17, 19, 23, and 25 were rejected under 35 U.S.C. § 102(b) as being anticipated by Scheiner et al. (U.S. Patent No. 6,212,434) (hereinafter “Scheiner”). Applicant respectfully traverses on the ground that there is no *prima facie* case of anticipation.

Claim 1:

Claim 1 recites a lead assembly comprising, among other things, “[a] first portion of [a] fixation helix supported by [a] piston forming a drive mechanism including one or more helical drive grooves, the helical drive grooves defined in part by an outer surface of the piston and successive turns of the fixation helix.” Applicant cannot find, nor did the Office Action identify, in Scheiner any disclosure of the formation of a drive mechanism from the coupling of the fixation helix and the piston, as recited in claim 1. Rather, the Office Action asserted (in isolation) that a collar element 922 of Scheiner surrounding a fixation helix disclosed the claimed piston, while external thread elements 920 disposed about the collar element disclosed the

claimed drive mechanism. (Office Action at pp. 2-3). That is to say, the asserted drive mechanism in Scheiner is not formed by the coupling of the fixation helix and the piston as claimed, but rather is an integrated portion of the asserted piston. According to the Federal Circuit, “[a]nticipation requires the disclosure in a single prior art reference of each element of the claim under consideration.” *W.L. Gore & Assocs. V. Garlock, Inc.*, 721 F.2d 1540, 200 USPQ 303, 313 (Fed. Cir. 1983). It is not enough, however, that the reference discloses all the claimed elements in isolation. Rather, as stated by the Federal Circuit, the prior art reference must disclose each element of the claimed invention “*arranged as in the claim.*” *Lindemann Maschinenfabrik GmbH v. American Hoist & Derrick Co.*, 730 F.2d 1452, 221 USPQ 481, 485 (Fed. Cir. 1984) (emphasis added).

Not only were the claimed piston and drive mechanism inappropriately asserted in isolation by the Office Action, Applicant also cannot find in Scheiner any disclosure of “one or more helical drive grooves defined in part by an outer surface of the piston and successive turns of the fixation helix,” as further recited in claim 1. In fact, the structure of Scheiner does not allow for a drive groove defined by the outer surface of the piston and successive turns of the fixation helix to exist, as such elements are disposed on opposite sides of the asserted piston (i.e., the collar element 922). (See Scheiner at FIG. 39, illustrating that the fixation helix is disposed adjacent an interior surface of the collar element 922).

Because there is no *prima facie* case of anticipation of claim 1, Applicant respectfully requests withdrawal of this basis of rejection of such claim. Claims 2-6 and 24 are dependent on claim 1 and are patentable over Scheiner for the reasons stated above, in addition to the elements in such claims.

Claim 3:

Additionally, regarding claim 3, Applicant cannot find in Scheiner any disclosure of a lead assembly including a piston “wherein the piston has a recess wrapped around, and extending inwardly from, the outer surface thereof such that one or more portions of the recess are separated from one another by a non-recessed portion, and at least a portion of the first portion of the fixation helix is disposed within the recess,” as recited in claim 3. As discussed above, the fixation helix and the outer surface of the asserted piston (i.e., the collar element 922) of Scheiner are disposed on opposite sides of the piston. (See Scheiner at FIG. 39). It follows that

Scheiner cannot anticipate the subject matter of claim 3, as no portion of the fixation helix can be disposed in a recess extending inwardly from the outer surface of the asserted piston.

Further, the Office Action inherently acknowledges that certain elements of claim 3 are not disclosed in Scheiner. For example, the Office Action states “Scheiner et al. do not disclose that a non-recessed portion of a piston separates successive turns of a fixation helix.” (Office Action at p. 10).

Because there is no *prima facie* case of anticipation of claim 3, Applicant respectfully requests withdrawal of this basis of rejection of such claim. Claims 4-6 are dependent on claim 3 and are patentable over Scheiner for the reasons stated above, in addition to the elements in such claims.

Claim 4:

Additionally, regarding claim 4, Applicant cannot find in Scheiner any disclosure of a lead assembly including a piston having a recess wrapped around, and extending inwardly from, the outer surface thereof such that one or more portions of the recess are separated from one another by a non-recessed portion, and at least a portion of the first portion of the fixation helix is disposed within the recess and “the recess has a helical shape,” as recited or incorporated in claim 4. Further, the Office Action expressly acknowledges that all elements of claim 4 are not disclosed in Scheiner when it states that such reference does not disclose “recessing at least a part of a first portion of a fixation helix within a helical groove.” (Office Action at p. 10).

Because there is no *prima facie* case of anticipation of claim 4, Applicant respectfully requests withdrawal of this basis of rejection of such claim.

Claim 8:

Claim 8 recites a lead assembly comprising, among other things, “[a] fixation helix coupled with, and protruding radially around, [a] piston along a first longitudinal portion of the fixation helix, the first portion of the fixation helix coupled with the piston forming a drive mechanism that rides along the guide allowing at least one of advancing or retracting of the fixation helix relative to the lead body.” To this end, Applicant hereby incorporates by reference the relevant case law and arguments asserted above in association with claims 1, 3, and 4 (i.e., Scheiner does not disclose the formation of a drive mechanism from the coupling of the fixation

helix and the asserted piston (collar element 922); and further, the fixation helix and the outer surface of the asserted piston are on opposite sides of the piston - accordingly, the fixation helix cannot protrude radially around the asserted piston when coupled thereto - both of which are recited elements of claim 8).

Because there is no *prima facie* case of anticipation of claim 8, Applicant respectfully requests withdrawal of this basis of rejection of such claim. Claims 9-14 and 25 are dependent on claim 8 and are patentable over Scheiner for the reasons stated above, in addition to the elements in such claims.

Claim 11:

Additionally, regarding claim 11, Applicant cannot find in Scheiner any disclosure of a lead assembly including a fixation helix “wherein the fixation helix is coupled with the piston along a recess extending inward from an outer surface of the piston, a first portion of the recess separated from a second portion of the recess by a non-recessed piston portion,” as recited in claim 11. To this end, Applicant hereby incorporates by reference the relevant arguments asserted above in association with claim 3 (i.e., the fixation helix and the outer surface of the asserted piston (collar element 922) of Scheiner are on opposite sides of the piston – accordingly, no portion of the fixation helix can be disposed in a recess extending inward from the outer surface; and further, the Office Action impliedly acknowledges that Scheiner does not disclose a non-recessed portion of a piston which separates successive turns of a fixation helix, both of which are recited elements of claim 11).

Because there is no *prima facie* case of anticipation of claim 11, Applicant respectfully requests withdrawal of this basis of rejection of such claim.

Claim 15:

Claim 15 recites a lead assembly comprising, among other things, “[a] first portion of [a] fixation helix supported by [a] piston forming a drive mechanism that longitudinally advances and retracts the fixation helix; and a housing including a guide therein, the guide extending from an inner surface of the housing and adapted to interact directly with the first portion of the fixation helix.” To this end, Applicant hereby incorporates by reference the relevant case law and arguments asserted above in association with claim 1 (i.e., Scheiner does not disclose the

formation of a drive mechanism from the coupling of the fixation helix and the asserted piston (collar element 922)). Additionally, the Office Action acknowledges that the fixation helix of Scheiner does not interact directly with the asserted housing guide (i.e., internal thread elements 926) as claimed, but rather interacts by way of the asserted piston (i.e., collar element 922). (Office Action at p. 4).

Because there is no *prima facie* case of anticipation of claim 15, Applicant respectfully requests withdrawal of this basis of rejection of such claim. Claims 16-18 and 26 are dependent on claim 15 and are patentable over Scheiner for the reasons stated above, in addition to the elements in such claims.

Claim 17:

Additionally, regarding claim 17, Applicant cannot find in Scheiner any disclosure of a lead assembly including an active fixation helix “wherein the active fixation helix is recessed within an outer axial surface of the piston,” as recited in claim 17. To this end, Applicant hereby incorporates by reference the relevant arguments asserted above in association with claim 3 (i.e., the fixation helix and the outer surface of the asserted piston (collar element 922) of Scheiner are disposed on opposite sides of the piston - accordingly, no portion of the fixation helix can be recessed within an outer axial surface portion of the piston – as recited in claim 17).

Because there is no *prima facie* case of anticipation of claim 17, Applicant respectfully requests withdrawal of this basis of rejection of such claim.

Claim 19:

Claim 19 recites a method comprising, among other things, providing a lead assembly including “a fixation helix supported by, and protruding radially around, [a] piston at a first portion of the fixation helix, the first portion of the fixation helix forming a drive mechanism; . . . and longitudinally driving the fixation helix with the drive mechanism, including moving the first portion of the fixation helix directly along [a housing] guide.” To this end, Applicant hereby incorporates by reference the relevant case law and arguments asserted above in association with claims 1 and 15 (i.e., Scheiner does not disclose the formation of a drive mechanism from the coupling of the fixation helix and the asserted piston (collar element 922); and further, the Office Action acknowledges that the fixation helix of Scheiner does not interact

directly with the asserted housing guide (internal thread elements 926) as claimed, but rather interacts by way of the asserted piston).

Because there is no *prima facie* case of anticipation of claim 19, Applicant respectfully requests withdrawal of this basis of rejection of such claim. Claims 20-23 are dependent on claim 19 and are patentable over Scheiner for the reasons stated above, in addition to the elements in such claims.

3. Claims 1-6, 8-12, 14-17, and 25 were rejected under 35 U.S.C. § 102(e) as being anticipated by Soltis et al. (U.S. Patent No. 6,704,605) (hereinafter “Soltis”). Applicant respectfully traverses on the ground that there is no *prima facie* case of anticipation.

Claim 1:

Claim 1 recites a lead assembly comprising, among other things, “[a] first portion of [a] fixation helix supported by [a] piston forming a drive mechanism including one or more helical drive grooves, the helical drive grooves defined in part by an outer surface of the piston and successive turns of the fixation helix.” Applicant cannot find, nor did the Office Action identify, in Soltis any disclosure of the formation of a drive mechanism from the coupling of the fixation helix and the piston, as recited in claim 1. Rather, the Office Action asserted (in isolation) that a piston member element 36 having a reduced diameter portion which supports a fixation helix disclosed the claimed piston and fixation helix, while external thread elements 38 disposed about a non-reduced diameter portion of the piston member element disclosed the claimed drive mechanism. (Office Action at p. 6). That is to say, the asserted drive mechanism in Soltis is not formed by the coupling of the fixation helix and the piston as claimed, but rather is an integrated portion of the piston member element 36. According to the Federal Circuit, “[a]nticipation requires the disclosure in a single prior art reference of each element of the claim under consideration.” *W.L. Gore & Assocs. V. Garlock, Inc.*, 721 F.2d 1540, 200 USPQ 303, 313 (Fed. Cir. 1983). It is not enough, however, that the reference discloses all the claimed elements in isolation. Rather, as stated by the Federal Circuit, the prior art reference must disclose each element of the claimed invention “*arranged as in the claim.*” *Lindemann Maschinenfabrik GmbH v. American Hoist & Derrick Co.*, 730 F.2d 1452, 221 USPQ 481, 485 (Fed. Cir. 1984) (emphasis added).

Not only were the claimed piston, fixation helix, and drive mechanism inappropriately asserted in isolation by the Office Action, Applicant also cannot find in Soltis any disclosure of “one or more helical drive grooves defined in part by an outer surface of the piston and successive turns of the fixation helix,” as further recited in claim 1. Rather, Soltis (as identified by the Office Action) discloses helical drive grooves defined by external threads of the piston member element 36.

Because there is no *prima facie* case of anticipation of claim 1, Applicant respectfully requests withdrawal of this basis of rejection of such claim. Claims 2-6 and 24 are dependent on claim 1 and are patentable over Soltis for the reasons stated above, in addition to the elements in such claims.

Claim 3:

Additionally, regarding claim 3, Applicant cannot find in Soltis any disclosure of a lead assembly including a piston “wherein the piston has a recess wrapped around, and extending inwardly from, the outer surface thereof such that one or more portions of the recess are separated from one another by a non-recessed portion, and at least a portion of the first portion of the fixation helix is disposed within the recess,” as recited in claim 3. Rather, the Office Action asserted (in isolation and as prohibited by *Lindemann Maschinenfabrik GmbH*) that the external thread elements 38 and the recesses therebetween disclose the claimed recess and non-recessed portions, while the reduced diameter portion of the piston member element 36 disclosed the claimed recess to which the fixation helix is disposed within. (Office Action at p. 7). As clearly recited in claim 3, the recess in which the fixation helix is disposed within is that recess which “wrap[s] around, and extend[s] inwardly from, the outer surface thereof such that one or more portions of the recess are separated from one another by a non-recessed portion.” For Soltis to anticipate claim 3, the fixation helix therein would have to be disposed within the recesses of the external thread elements 38 and not the reduced diameter portion of the piston member element 36.

Because there is no *prima facie* case of anticipation of claim 3, Applicant respectfully requests withdrawal of this basis of rejection of such claim. Claims 4-6 are dependent on claim 3 and are patentable over Soltis for the reasons stated above, in addition to the elements in such claims.

Claim 8:

Claim 8 recites a lead assembly comprising, among other things, “[a] fixation helix coupled with, and protruding radially around, [a] piston along a first longitudinal portion of the fixation helix, the first portion of the fixation helix coupled with the piston forming a drive mechanism that rides along the guide allowing at least one of advancing or retracting of the fixation helix relative to the lead body.” To this end, Applicant hereby incorporates by reference the relevant case law and arguments asserted above in association with claim 1 (i.e., Soltis does not disclose the formation of a drive mechanism from the coupling of the fixation helix and the asserted piston member element).

Because there is no *prima facie* case of anticipation of claim 8, Applicant respectfully requests withdrawal of this basis of rejection of such claim. Claims 9-14 and 25 are dependent on claim 8 and are patentable over Soltis for the reasons stated above, in addition to the elements in such claims.

Claim 11:

Additionally, regarding claim 11, Applicant cannot find in Soltis any disclosure of a lead assembly including a fixation helix “wherein the fixation helix is coupled with the piston along a recess extending inward from an outer surface of the piston, a first portion of the recess separated from a second portion of the recess by a non-recessed piston portion,” as recited in claim 11. To this end, Applicant hereby incorporates by reference the relevant arguments asserted above in association with claim 3 (i.e., the Office Action asserted the claimed elements in isolation as prohibited by *Lindemann Maschinenfabrik GmbH* - for Soltis to anticipate claim 11, the fixation helix therein would have to be disposed within the recesses of the external thread elements 38 and not the reduced diameter portion of the piston member element 36).

Because there is no *prima facie* case of anticipation of claim 11, Applicant respectfully requests withdrawal of this basis of rejection of such claim.

Claim 15:

Claim 15 recites a lead assembly comprising, among other things, “[a] first portion of [a] fixation helix supported by [a] piston forming a drive mechanism that longitudinally advances and retracts the fixation helix; and a housing including a guide therein, the guide extending from

an inner surface of the housing and adapted to interact directly with the first portion of the fixation helix.” To this end, Applicant hereby incorporates by reference the relevant case law and arguments asserted above in association with claim 1 (i.e., Soltis does not disclose the formation of a drive mechanism from the coupling of the fixation helix and the asserted piston member element). Additionally, the Office Action acknowledges that the fixation helix of Soltis does not interact directly with the asserted housing guide (i.e., internal thread elements) as claimed, but rather interacts by way of the asserted piston member element).

Because there is no *prima facie* case of anticipation of claim 15, Applicant respectfully requests withdrawal of this basis of rejection of such claim. Claims 16-18 and 26 are dependent on claim 15 and are patentable over Soltis for the reasons stated above, in addition to the elements in such claims.

§103 Rejection of the Claims

4. Claims 13 and 18 were rejected under 35 U.S.C. § 103(a) as being unpatentable over Scheiner as applied to claims 8 and 15 above, and in view of Bisping (U.S. Patent No. 4,282,885) (hereinafter “Bisping”). Applicant respectfully traverses on the ground that there is no *prima facie* case of obviousness.

Claims 13 and 18:

Claims 13 and 18 recite a lead assembly comprising, among other things, a fixation helix coupled with a piston “along a helical recess within the piston” or “via one or more recessed groove portions separated by a non-recessed piston portion,” respectively. The Office Action expressly acknowledges that Scheiner does not disclose such claimed subject matter. (See Office Action at p. 9). Instead, the Office Action attempts to rely on Bisping to establish these missing elements asserting that it would have been obvious at the time of the invention to modify the coupling structure of Scheiner as taught by Bisping “to provide stable guidance for the relative movement between the helix and the piston during implantation and extraction.” (Office Action at p. 9). However, Scheiner expressly teaches against relative movement between the helix and the piston during implantation and extraction. For example, Scheiner states:

During use, the terminal pins [] are rotated which causes the collar 922 to rotate. As the collar 922 is rotated and the external threads 920 and the internal threads 926 engage, the active fixation element 970 moves along the axis of the lead 900.

(Scheiner at col. 28, ll. 1-5; *see also* FIG. 39). Thus, because Scheiner requires no relative movement to exist between the fixation helix and the asserted piston (i.e., the collar element) such that there is direct force transmission between the terminal pin, the piston, and ultimately the helix, combining Scheiner with Bisping would seemingly destroy the operability of Scheiner. According to the Federal Circuit, “[i]f references taken in combination would produce a ‘seemingly inoperative device,’ [] such references teach away from the combination and thus cannot serve as predicates for a *prima facie* case of obviousness.” *McGinley v. Franklin Sports Inc.*, 262 F.3d 1339, 60 USPQ2d 1001, 1010 (Fed. Cir. 2001). Therefore, such combination of Scheiner and Bisping is improper, and fails to establish all elements of claims 13 and 18.

Because there is no *prima facie* case of obviousness of claims 13 and 18, Applicant respectfully requests withdrawal of this basis of rejection of such claims.

5. Claims 20-21 were rejected under 35 U.S.C. § 103(a) as being unpatentable over Scheiner in view of Bisping. Applicant respectfully traverses on the ground that there is no *prima facie* case of obviousness.

Claims 20 and 21:

Claims 20 and 21 recite a method comprising, among other things, recessing “at least a part of the first portion of the fixation helix within the piston such that a non-recessed portion of the piston separates successive turns of the fixation helix” and “approximately 1/3 to 1/2 of a diameter of the fixation helix within the piston such that successive turns of the fixation helix are separated by a non-recessed piston portion,” respectively. The Office Action expressly acknowledges that Scheiner does not disclose such claimed subject matter. (*See* Office Action at p. 10). Instead, the Office Action attempts to rely on Bisping to establish these missing elements. To this end, Applicant hereby incorporates by reference the relevant arguments asserted above in association with claims 13 and 18 (i.e., combining Scheiner with Bisping would seemingly destroy the operability of Scheiner). In addition, Scheiner teaches that the fixation helix should be disposed within the asserted piston (i.e., the collar element 922), whereas Bisping teaches that the fixation helix should be disposed around the asserted piston (i.e., the protective core element 23). In this way, Scheiner further teaches away from being combined with Bisping.

Because there is no *prima facie* case of obviousness of claim 20 and 21, Applicant respectfully requests withdrawal of this basis of rejection of such claims.

6. Claim 22 was rejected under 35 U.S.C. § 103(a) as being unpatentable over Scheiner in view of Smits (U.S. Patent No. 4,311,153) (hereinafter “Smits”). Applicant respectfully traverses on the ground that there is no *prima facie* case of obviousness.

Claim 22:

Claim 22 recites a method comprising, among other things, “recessing at least a part of [a] first portion of [a] fixation helix within a helical groove of [a] piston.” The Office Action expressly acknowledges that Scheiner does not disclose such claimed subject matter. (*See Office Action* at p. 10). Instead, the Office Action attempts to rely on Smits to establish these missing elements. However, Smits – like Bisping – relies on relative movement between the fixation helix and the asserted piston therein to allow the helix to come into contact with bodily tissue. As discussed above in association with claims 13 and 18 and hereby expressly incorporated herein, Scheiner teaches against relative movement between the helix and the piston during implantation and extraction.

Because there is no *prima facie* case of obviousness of claim 22, Applicant respectfully requests withdrawal of this basis of rejection of such claim.

7. Claims 24 and 26 were rejected under 35 U.S.C. § 103(a) as being unpatentable over Scheiner as applied to claims 1 and 15 above, and in view of Berthelsen et al. (U.S. Patent No. 5,002,067) (hereinafter “Berthelsen”). Applicant respectfully traverses on the ground that there is no *prima facie* case of obviousness.

Claims 24 and 26:

Claims 24 and 26 recite a lead assembly comprising, among other things, a housing portion “wherein the housing portion comprises a molded component” and “a fluoromarker coupled with a portion of the housing,” respectively. The Office Action expressly acknowledges that Scheiner does not disclose such claimed subject matter. (*See Office Action* at p. 11). Instead, the Office Action attempts to rely on Berthelsen to establish these missing elements

asserting, in part, it would have been obvious at the time of the invention to modify the asserted housing portion of Scheiner (i.e., element 924) with the molded housing of Berthelsen “to provide a robust device.” (Office Action at p. 11).

The Office Action appears to pick and choose among individual elements of assorted references (in this case, Scheiner and Berthelsen) to recreate the claimed invention without some teaching or motivation in the references to support their use in the particular claimed combination, as prohibited by the Federal Circuit’s holding in *Symbol Technologies, Inc. v. Symbol Technologies, Inc. v. Opticon, Inc.*, 935 F.2d 1569, 19 U.S.P.Q.2d 1241 (Fed. Cir. 1991). As one example, Scheiner relies on internal thread elements 926 of the housing 924 to advance the fixation helix, whereas Berthelsen discloses a housing 10 having no internal threads but rather “an internal cylindrical lumen 12.” (Scheiner at col. 28, ll. 1-5; Berthelsen at col. 2, ll. 40-44). In light of at least this, one of ordinary skill in the art at the time of the invention considering Scheiner would not have been motivated to look to Berthelsen to modify their respective lead structures, and especially their respective housings, as claimed by Applicant.

Because there is no *prima facie* case of obviousness of claims 24 and 26, Applicant respectfully requests withdrawal of this basis of rejection of such claims.

8. Claims 13 and 18 were rejected under 35 U.S.C. § 103(a) as being unpatentable over Soltis as applied to claims 8 and 15 above, and in view of Bisping. Applicant respectfully traverses on the ground that there is no *prima facie* case of obviousness.

Claims 13 and 18:

Claims 13 and 18 recite a lead assembly comprising, among other things, a fixation helix coupled with a piston “along a helical recess within the piston” or “via one or more recessed groove portions separated by a non-recessed piston portion,” respectively. The Office Action expressly acknowledges that Soltis does not disclose such claimed subject matter. (See Office Action at p. 11). Instead, the Office Action attempts to rely on Bisping to establish these missing elements asserting that it would have been obvious at the time of the invention to modify the coupling structure of Soltis as taught by Bisping “to provide stable guidance for the relative movement between the helix and the piston during implantation and extraction.” (Office Action

at p. 12). However, Soltis expressly teaches against relative movement between the helix and the piston during implantation and extraction. For example, Soltis states:

A screw helix, electrode and anchor or fixation device 40 has a proximal end 42 fixed to the distal end 43 of the piston member 36.

(Soltis at col. 3, ll. 64-67; *see also* FIG. 2A). Thus, because Soltis requires no relative movement to exist between the fixation helix and the piston member such that there is direct force transmission between these elements, combining Soltis with Bisping would seemingly destroy the operability of Soltis. According to the Federal Circuit, “[i]f references taken in combination would produce a ‘seemingly inoperative device,’ [] such references teach away from the combination and thus cannot serve as predicates for a *prima facie* case of obviousness.” *McGinley v. Franklin Sports Inc.*, 262 F.3d 1339, 60 USPQ2d 1001, 1010 (Fed. Cir. 2001). Therefore, in accordance with the Federal Circuit’s holding in *McGinley*, because the combination of Soltis and Bisping destroys operability of at least one of these references, such combination is improper and fails to establish all elements of claims 13 and 18.

Because there is no *prima facie* case of obviousness of claims 13 and 18, Applicant respectfully requests withdrawal of this basis of rejection of such claims.

9. Claims 24 and 26 were rejected under 35 U.S.C. § 103(a) as being unpatentable over Soltis as applied to claims 1 and 15 above, and in view of Berthelsen. Applicant respectfully traverses on the ground that there is no *prima facie* case of obviousness.

Claims 24 and 26:

Claims 24 and 26 recite a lead assembly comprising, among other things, a housing portion “wherein the housing portion comprises a molded component” and “a fluoromarker coupled with a portion of the housing,” respectively. The Office Action expressly acknowledges that Soltis does not disclose such claimed subject matter. (*See* Office Action at p. 12). Instead, the Office Action attempts to rely on Berthelsen to establish these missing elements asserting, in part, it would have been obvious at the time of the invention to modify the asserted housing portion of Soltis (i.e., element 32) with the molded housing of Berthelsen “to provide a robust device.” (Office Action at p. 12).

The Office Action appears to pick and choose among individual elements of assorted references (in this case, Soltis and Berthelsen) to recreate the claimed invention without some teaching or motivation in the references to support their use in the particular claimed combination, as prohibited by the Federal Circuit's holding in *Symbol Technologies, Inc. v. Symbol Technologies, Inc. v. Opticon, Inc.*, 935 F.2d 1569, 19 U.S.P.Q.2d 1241 (Fed. Cir. 1991). As one example, Soltis relies on internal thread elements 38 of the housing 32 to advance the piston member 36 and thus the fixation helix 40, whereas Berthelsen discloses a housing 10 having no internal threads but rather "an internal cylindrical lumen 12." (Soltis at FIG. 2A; Berthelsen at col. 2, ll. 40-44). In light of at least this, one of ordinary skill in the art at the time of the invention considering Soltis would not have been motivated to look to Berthelsen to modify their respective lead structures, and especially their respective housings, as claimed by Applicant.

Because there is no *prima facie* case of obviousness of claims 24 and 26, Applicant respectfully requests withdrawal of this basis of rejection of such claims.

10. Claims 19, 22, and 23 were rejected under 35 U.S.C. § 103(a) as being unpatentable over Soltis in view of Smits. Applicant respectfully traverses on the ground that there is no *prima facie* case of obviousness.

Claims 19:

Claim 19 recites a method comprising, among other things, "providing a lead assembly including . . . a fixation helix supported by, and protruding radially around, [a] piston at a first portion of the fixation helix . . . and longitudinally driving the fixation helix with the drive mechanism, including moving the first portion of the fixation helix directly along the guide." The Office Action expressly acknowledges that Soltis does not disclose such claimed subject matter. (See Office Action at p. 13). Instead, the Office Action attempts to rely on Smits to establish these missing elements. For example, the Office Action asserts "Smits discloses moving a first portion of a fixation helix along a guide." (Office Action at p. 13). However, Applicant submits that neither Soltis nor Smits discloses moving a first portion of a fixation helix directly along a housing guide, wherein the first portion of the helix is that portion of the helix which is supported by the piston. Therefore, such combination fails to establish all elements of claim 19, arranged as in such claim.

Because there is no *prima facie* case of obviousness of claim 19, Applicant respectfully requests withdrawal of this basis of rejection of such claim. Claims 20-23 are dependent on claim 19 and are patentable over Soltis and Smits for the reasons stated above, in addition to the elements in such claims.

Claim 22:

Claim 22 recites a method comprising, among other things, “recessing at least a part of [a] first portion of [a] fixation helix within a helical groove of [a] piston.” The Office Action expressly acknowledges that Soltis does not disclose such claimed subject matter. (*See* Office Action at pp. 13-14). Instead, the Office Action attempts to rely on Smits to establish these missing elements. However, Smits – like Bisping – relies on relative movement between the fixation helix and the asserted piston therein to allow the helix to come in contact with bodily tissue. As discussed above in association with claims 13 and 18 and hereby expressly incorporated herein, Soltis clearly teaches against relative movement between the helix and the piston during implantation and extraction.

Because there is no *prima facie* case of obviousness of claim 22, Applicant respectfully requests withdrawal of this basis of rejection of such claim.

11. Claims 20 and 21 were rejected under 35 U.S.C. § 103(a) as being unpatentable over Soltis and Smits, and further in view of Bisping. Applicant respectfully traverses on the ground that there is no *prima facie* case of obviousness.

Claims 20 and 21:

Claims 20 and 21 recite a method comprising, among other things, recessing “at least a part of the first portion of the fixation helix within the piston such that a non-recessed portion of the piston separates successive turns of the fixation helix” and “approximately 1/3 to 1/2 of a diameter of the fixation helix within the piston such that successive turns of the fixation helix are separated by a non-recessed piston portion,” respectively. The Office Action expressly acknowledges that neither Soltis nor Smits discloses such claimed subject matter. (*See* Office Action at p. 14). Instead, the Office Action attempts to rely on Bisping to establish these missing elements. To this end, Applicant hereby incorporates by reference the relevant arguments

asserted above in association with claims 13 and 18 (i.e., combining Soltis and Smits with Bisping would seemingly destroy the operability of at least Soltis).

Because there is no *prima facie* case of obviousness of claim 20 and 21, Applicant respectfully requests withdrawal of this basis of rejection of such claims.

Reservation of Rights:

In the interest of clarity and brevity, Applicant may not have addressed every assertion made in the Office Action. Applicant's silence regarding any such assertion does not constitute any admission or acquiescence. Applicant reserves all rights not exercised in connection with this response, such as the right to challenge or rebut any tacit or explicit characterization of any reference or of any of the present claims, the right to challenge or rebut any asserted factual or legal basis of any of the rejections, the right to swear behind any cited reference such as provided under 37 C.F.R. § 1.131 or otherwise, or the right to assert co-ownership of any cited reference. Applicant does not admit that any of the cited references or any other references of record are relevant to the present claims, or that they constitute prior art. To the extent that any rejection or assertion is based upon the Examiner's personal knowledge, rather than any objective evidence of record as manifested by a cited prior art reference, Applicant timely objects to such reliance on Official Notice, and reserves all rights to request that the Examiner provide a reference or affidavit in support of such assertion, as required by MPEP § 2144.03. Applicant reserves all rights to pursue any canceled claims in a subsequent patent application claiming the benefit of priority of the present patent application, and to request rejoinder of any withdrawn claim, as required by MPEP § 821.04.

Serial Number: 10/673,926

Filing Date: September 29, 2003

Title: EXTENDABLE AND RETRACTABLE LEAD WITH AN ACTIVE FIXATION ASSEMBLY**CONCLUSION**

Applicant respectfully submits that the claims are in condition for allowance, and notification to that effect is earnestly requested. The Examiner is invited and encouraged to telephone Applicant's attorneys Greg W. Smock at (612) 373-6956 or Catherine I. Klima-Silberg at (612) 359-3276 to facilitate prosecution of this application.

If necessary, please charge any additional fees or credit overpayment to Deposit Account No. 19-0743.

Respectfully submitted,

GREGORY L. SUNDBERG

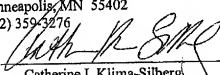
By his Representatives,

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Date

3/7/07

By


Catherine I. Klima-Silberg
Reg. No. 40,052

CERTIFICATE UNDER 37 CFR 1.8: The undersigned hereby certifies that this correspondence is being filed using the USPTO's electronic filing system EFS-Web, and is addressed to: Mail Stop Amendment, Commissioner of Patents, P.O. Box 1450, Alexandria, VA 22313-1450 on this 7 day of March 2007.

Name

Signature